DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

g3127d

February 8, 2002

VIA FEDERAL EXPRESS

Ralph L. Bass
President
Bass & Boney, Inc.
3708 Sweeten Creek Road
Chapel Hill, North Carolina 27514

WARNING LETTER
(02-ATL-20)

Dear Mr. Bass:

This letter is in reference to your firm's marketing a variety of "salt spool" products distributed under the "ACNE-LTD III," "DERMATITIS-LTD III," and "ROSACEA-LTD III" labels. The products are promoted for over-the-counter treatment of acne, dermatitis, and rosacea respectively. According to product labeling and promotional literature, the products contain zinc oxide, sodium chloride, sulfur, iron oxide, magnesium stearate, and polyethylene glycol as ingredients.

Your "ACNE-LTD III" package insert (labeling) claims this product will "help to decrease inflammation of acne by dehydration" and that the product "works as a bactericide to help prevent pimples, as well as the red flushed areas and small blood capillaries typical of rosacea." This insert directs your customers to the www.acne-ltd.com website prior to product use. This site promotes your product as "GUARANTEED SUCCESS IN LIMITING ACNE" and as "the most effective method of treatment for adult acne."

Your "DERMATITIS-LTD III" package insert includes directions for use of the product. Statements of "Plaque-type psoriasis" and "Psoriasis vulgaris" are included in these directions. Also, this insert directs your customers to your website www.dermatitis-ltd.com prior to product use. The website promotes your product as "Guaranteed Success in Limiting Dermatitis," "designed for use on skin affected by any type of inflammation such as atopic eczema, adult, child and infantile seborrhiec, plaque-type psoriasis, guttate psoriasis, pustular psoriasis, or prythrodermic psoriasis," and "has more that 99% undiluted active ingredients." It is also promoted as "successful in reducing symptoms associated with dermatitis."

Your "ROSACEA-LTD III" package insert provides directions for use for the product. Statements include "the skin needs 45 to 60 days to heal and repair itself from rosacea." Customers are advised to "stop all other topical rosacea & acne medications." They are also directed to the www.rosacea-ltd.com website before beginning to use this product. That website promotes your product as "GUARANTEED SUCCESS IN LIMITING ROSACEA" and "ROSACEA-LTD III™" was designed specifically for skin that is sensitive or inflamed due to rosacea and seborrheic dermatitis."

Based on the intended uses established by the claims cited above, these products are drugs as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Over-the-counter (OTC) drug products are subject to final regulations [Title 21, Code of Federal Regulations (21 CFR), Part 330 (21 CFR 330)] and any specific drug product monographs. As labeled and formulated, your acne, dermatitis and rosacea products fail to meet all the requirements of the final OTC monographs.

These products are not generally recognized as safe and effective for the conditions noted. As labeled, promoted, and formulated "ACNE-LTD III" and "ROSACEA-LTD III" are subject to the acne final regulations found in 21 CFR 333.301, 333.310, 333.320, and 333.350. "DERMATITIS-LTD III" and "ROSACEA-LTD III" are subject to the final rule for drug products for the control of dandruff, seborrheic dermatitis, and psoriasis found in 21 CFR 358.701, 358.703, 358.710 and 358.750. The ingredients and labeling for these products do not comply with the final regulations.

Although the active ingredients in these products are not specifically identified on the product label, labeling distributed with the products promote the above listed ingredients for acne, rosacea, and/or dermatitis treatment. These ingredients are not permitted as active ingredients under the regulations in an OTC acne or dermatitis product. Because the labeling and formulation of "ACNE-LTD III," "DERMATITIS-LTD III," and "ROSACEA-LTD III," do not comply with the final regulations, your products are "new drugs" (Section 201(p) of the Act) which may not be legally marketed in the United States without an approved New Drug Application (Section 505).

Also, these products are misbranded (Section 502(f)(1) and Section 502(f)(2) of the Act) for failure to fully comply with the final regulations covering topical acne and/or dermatitis products under 21 CFR Parts 333.301, 358.701. The labeling fails to bear indications, adequate directions for use, and warning statements as required by the final monographs (21 CFR Parts 333.350, 358.750). Furthermore, "ROSACEA-LTD III" is misbranded (Section 502(f)(1) of the Act) in that its labeling does not contain adequate directions for use as this term is defined in 21 CFR Part 201.5 since the condition of rosacea is not amenable to self diagnosis and treatment by the laity.

These products are also misbranded (Section 502(o) of the Act) in that the drugs were manufactured and repacked in facilities which are not duly registered with FDA and the products are not listed as required by Section 510(j) of the Act.

Investigator Ruble also documented deviations from the Current Good Manufacturing Practice Regulations (21 CFR Part 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act. You could provide no documentation that any finished product testing had ever been conducted on any of the formulations used in your products. Your supplier provides no Certificates of Analysis and in fact the supplier advised you that no testing was being performed.

You could provide no formalized specifications for any of the formulations used in your products. You could provide no details as to the manufacturing process itself or the actual ingredients used in your product. The contract provided by your supplier differs from the ingredients listed in your labeling. The latest formulation provided by your supplier indicated that no sulfur is used in Formulation II. This spool also contained iron oxide and copper oxide, which are not included in the ingredients inserts. There appears to be no formal controls over changes made in the formulation of your products.

You have failed to properly respond to and investigate complaints involving product quality. Returned product was simply discarded without any further testing or investigation being conducted.

The above list of violations is not meant to be an all-inclusive list of deficiencies by your firm. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The above Good Manufacturing Practice deviations were included on the Inspectional Observations (FDA 483) which was issued to and discussed with you at the conclusion of the inspection. You are responsible for investigating and determining the causes of the violations identified by the FDA.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending New Drug Applications, Abbreviated New Drug Applications, or export approval requests may not be approved until the above violations are corrected. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to seizure (Section 304 of the Act) and/or injunction (Section 302 of the Act).

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should include copies of any revised labeling, promotional materials, product inserts, and web pages. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District